American Academy of Orthopaedic Surgeons®

AAOS American Association of Orthopaedic Surgeons

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August 25, 1999

Jane E. Henney, MD
Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lane
Rockville, Maryland 20852

Dear Dr. Henney:

The American Academy of Orthopaedic Surgeons, representing over 16,000 Board certified orthopaedic surgeons, is pleased to take this opportunity to express our support for the reclassification of the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis preamendment Class III orthopaedic medical devices. These devices were listed in the proposed rule in the Federal Register that was published on Friday, May 28, 1999. (Docket No. 97P-0354).

We share the concerns of FDA in ensuring that safe and effective products enter the marketplace. We remain committed to protecting consumers and our patients, while at the same time making sure that the latest technologies in safe orthopaedic devices come to the marketplace through streamlined regulatory review.

The orthopaedic clinical and research community has worked closely with the Orthopaedic Surgical Manufacturers Association (OSMA) to develop the petitions in support of the reclassification of these two orthopaedic devices, which were formally submitted to the FDA in July 1997. Many Academy Fellows provided balanced expertise and clinical experience to assemble the supporting data for these reclassification petitions. We believe that these data represent the best clinical evidence to date to support the reclassification of these devices from Class III to Class II.

Specifically documented clinical experience and peer-reviewed, published clinical results provide reasonable assurances of the safety and effectiveness of the devices as well as establish the risks associated with the devices that are controllable through adherence to standards, appropriate preclinical testing, labeling, and good surgical technique.

97P-0354

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Initially, during the late 1970's the Orthopaedic and Rehabilitation Devices Panel considered recommendations on the placement of total shoulder prostheses and assigned the devices to Class III. The rationale at that time was that there was not sufficient long-term clinical data on total shoulder arthroplasty. In the following two decades, a considerable body of peer-reviewed, published clinical results support the safety and efficacy of these devices. The Orthopaedic and Rehabilitative Devices Panel unanimously recommended that the shoulder prosthesis be reclassified from Class III to Class II at a public meeting in January 1998.

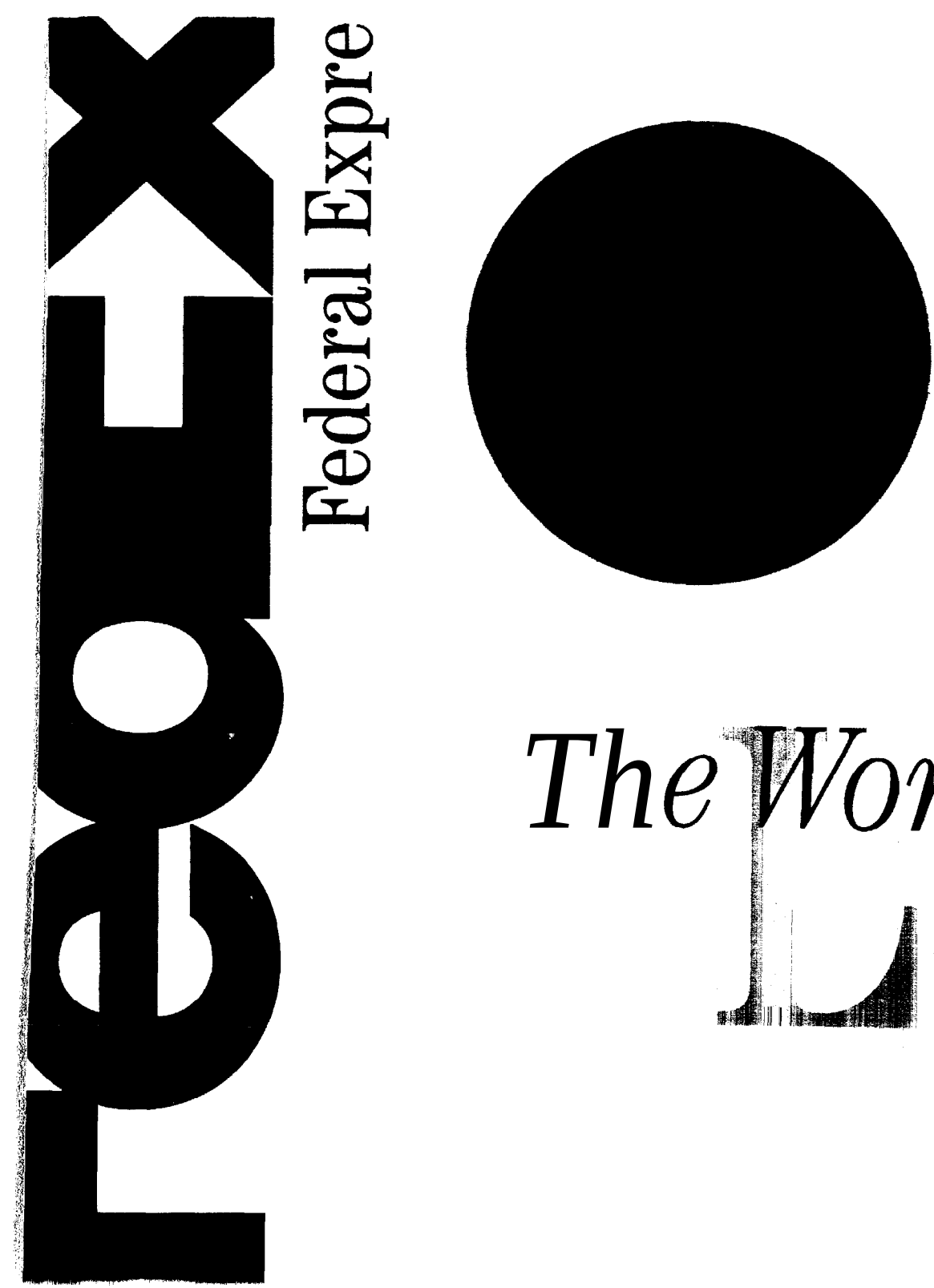
It is appropriate that shoulder joint metal/polymer/metal nonconstrained and semi-constrained, porous-coated, uncemented prostheses now be reclassified as Class II devices.

We commend FDA in its decision to reclassify these orthopaedic devices, and we look forward to continuing to work with you in the future in the reclassification of other orthopaedic devices for which we believe clinical data support their designation as Class II devices.

Thank you for your actions in this matter.

Sincerely,

William W. Tipton, Jr., MD
Executive Vice President



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